510k Summary K121827

SEP 13 2012

GE Healthcare

GSI Viewer with VUE Option
510(k) Premarket Notification

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: June 20th, 2012

Submitter: GE Medical Systems SCS
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GE Healthcare
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Device: Trade Name: GSI Viewer with VUE Option

Common/Usual Name: GSI Viewer with MSI Option

Classification Name: 21CFR 892.1750 Computed Tomography X-Ray system

Product Code: JAK

Predicate Devices: K120833 **Discovery CT750 HD**

Device Description: The unmodified device Discovery CT750 HD (K120833) offers the Gemstone Spectral Imaging (GSI) capability that uses rapid kV switching to acquire the dual energy samples almost simultaneously. This enables generation of material density data that can be used for the separation of materials and derivation of monochromatic spectral images using a projection based reconstruction algorithm.

GSI Viewer is a post processing visualization tool on the Discovery CT750 HD system that allows users to view and process spectral images acquired by the GSI scan modes. It allows for the review of monochromatic energy images at user selectable energy levels, detailed analysis using material decomposed images (such as water-iodine, water calcium, etc.), and complementary information using the Effective-Z images by providing an estimate of the protons' effective atomic number in a voxel.

The modification being introduced is the VUE (Virtual Unenhanced Exam) option that produces a material suppressed image at a given

monochromatic energy in the conventional CT Hounsfield Units.

This modification is based on the existing capability of the predicate device that generates material separated images in the Material density (MD) space and is the subject of this pre-market notification.

Indication for Use:

The **GSI Viewer** accepts images from a CT System that can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.

GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used as an adjunct to current standard methods for evaluating stone etiology and composition.

Technology:

The GSI Viewer with VUE option employs the same technology as the that of the GSI Viewer on its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The GSI Viewer with VUE Option complies with voluntary standards as detailed in Section 9, 11 and 16 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Final acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, GSI Viewer with VUE option, did not require clinical studies to support substantial

equivalence.

Conclusion: GE Healthcare considers the GSI Viewer with VUE Option software application to be as safe, as effective, and its performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

GE Medical Systems SCS
% Ms. Helen Peng
Regulatory Affairs Leader
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WAUKESHA WI 53188

Re: K121827
Trade/Device Name: GSI Viewer with VUE Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 18, 2012
Received: June 21, 2012

Dear Ms. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **GSI Viewer with VUE Option**

Indications for Use:

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Prescription Use_X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K121827